SCHWARZ PHARMA

September 8, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Re: Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics, published May 1999 Docket No. 97D-0268

Dear Sir/Madam:

Schwarz Pharma, Inc. herein requests clarification of the necessity of water vapor permeation testing on unit-of-use containers. On page 1936 of USP 24/ NF 19, under chapter <671> Containers - Permeation, the statement is made that "where the manufacturer's unopened multiple-unit, single-unit, or unit-dose packages are used for dispensing the drug, such containers are exempt from the requirements of this test." However, in the guidance referenced above, this section on page 34 under III.G., Solid Oral Dosage Forms and Powders for Reconstitution, appears to contradict the statement in USP:

> Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets (USP <671>): This test measures the water vapor permeation of a single-unit or unit-dose container closure system and establishes acceptance criteria for five standards (*Class A-E* containers).

It should be noted that teleconferences were held between representatives from Schwarz Pharma, Inc., and Dr. D. Klein, Chairman of the Packaging Committee, on August 17, 22, and 23, 2000. Dr. Klein brought this concern to the committee's attention and suggested that Schwarz Pharma submit a comment to the Docket requesting clarification of this issue in the next revision of the guidance.

If additional information or clarification of this request is needed, please contact Donna Multhauf, Director, Regulatory Affairs, at 262-238-5224 or by facsimile, 262-238-0957. Thank you for your attention to this matter.

Sincerely,

SCHWARZ PHARMA, INC.

Elaine Cibulka for

Donna K. Multhauf
Director
Regulatory Affairs

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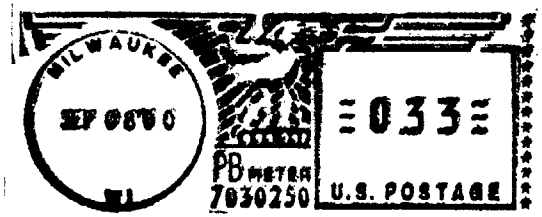

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